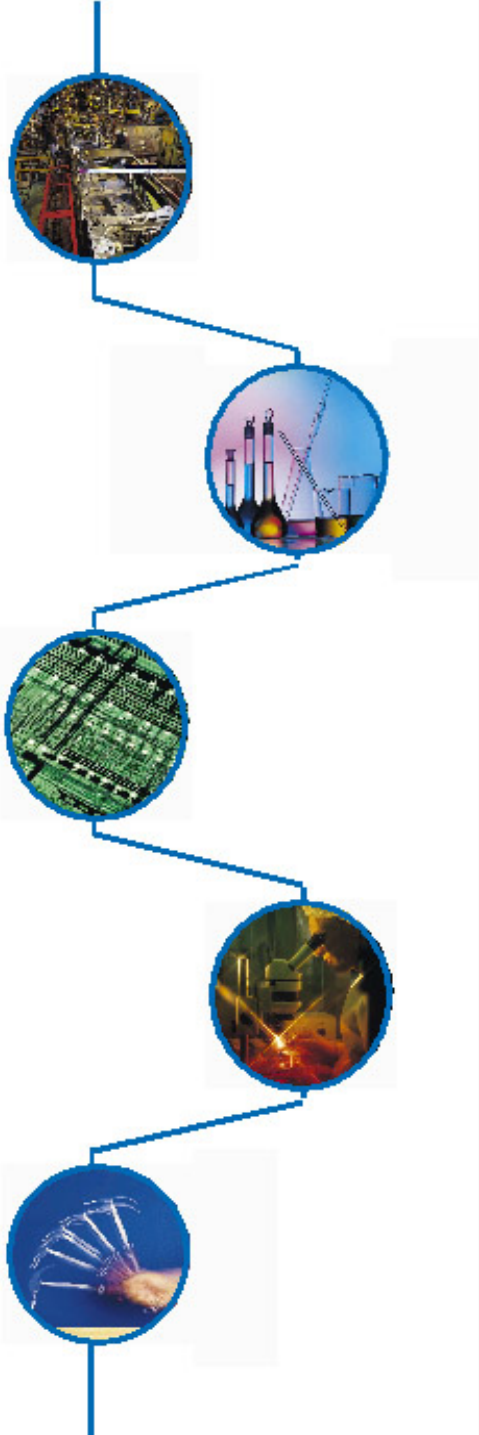

ANSI Accreditation Process for Product Certification Programs

美国国家标准学会
对产品认证方案的认可程序

2005 US-China Standards and Conformity Assessment Workshop

August 10, 2005

2005美中标准与合格评定研讨会

2005 年8月10日

ANSI's Roles and Responsibilities
美国国家标准学会的作用和职责

- to accredit U.S. Standards Developers, U.S. Technical Advisory Groups and Conformity Assessment programs
- to ensure integrity of the U.S. voluntary consensus standards system
- to provide regional and international access
- to offer a neutral policy forum
- Accredit certification programs

- 认可美国标准制定者、美国技术咨询小组和合格评定方案
- 确保美国自愿一致标准系统的完整
- 在区域和国际间牵线搭桥
- 提供中立的政策论坛
- 认可认证方案

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What is the Goal of ANSI's Accreditation program?
美国国家标准学会认可方案的目的是什么?

Results of ANSI accredited programs accepted as satisfying customer and regulatory requirements worldwide

经美国国家标准学会认可的方案所产生的结果已得到全球公认，被认为能满足顾客的要求和管理方面的要求

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Who Writes the “Rules”?
谁制定了“规则”?

- ***ISO*** - International Organization for Standardization Member Bodies participating from more than 100 Countries
- ***CASCO*** - Conformity Assessment Committee Participants from 62 Member Bodies

In conjunction with the International Electro technical Commission - IEC

- ***ISO*** – 由来自100多个国家的成员机构组成的国际标准化组织
- ***CASCO*** –由62个成员机构组成的合格评定委员会

与国际电工委员会- IEC联合制定

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Accreditation Program Elements
认可方案的要素

- Accessible to all stakeholders
- Mechanism for program review and revision
- Promotion of program and participation nationally and internationally

- 所有利益相关者都可以获取
- 方案审查与修改机制
- 方案推广及全国性和国际性的参与

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Overview / History
概览 / 历史

- ANSI Program issued first accreditation in 1972
- ISO/IEC Guide 65 accreditation criteria
- Accreditation of Telecom Cert Bodies started in the year 2000
- Recognized by NIST/NVCASE since June 2000 to accredited TCBs
- Recognized by NIST/NVCASE since October 2003 to Accredited TCBs in accordance with Industry Canada Requirements under APEC TEL MRA
- Recognized by Safety Quality Food Institute to operate the pilot accreditation program to accredited CB's on Food Safety

- 美国国家标准学会在1972年发出第一份认可书
- ISO/IEC指南65 认可标准
- 2000年开始对电信认证机构（TCBs）的认可工作
- 自2000年6月以来，得到国家标准和技术研究院和国家自愿合格评定系统评价组织（NIST/NVCASE)承认，成为获认可的TCBs
- 根据亚太经合组织有关电信设备合格评定的互认可安排，自2003年10月以来得到NIST/NVCASE的承认，成为符合加拿大工业部要求的获认可的TCBs
- 得到拟开展试点认可方案的安全质量食品协会承认，成为食品安全方面获认可的认证机构

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ANSI Accreditation Programs

Conformity Assessment (ISO/IEC 17011)

Standards

ISO/IEC Guide 65

ISO/IEC Guides 62 and 66

ISO/IEC 17024

ANSI Procedures *"Essential Requirements"*

Product Certifiers

ISO 9001 / 14001 Certifiers

Personnel Certifiers

Standards Developing Organizations and U.S. TAGs

ANSI Accredited Program PRODUCT CERTIFICATION

ANAB ANSI-ASQ National Accreditation Board

ANSI Accredited Program PERSONNEL CERTIFICATION

ANSI Accredited Standards Developer

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美国国家标准学会认可方案

合格评定 (国际标准化组织/国际电工委员会 17011)

标准

ISO/IEC 指南 65

ISO/IEC 指南62和 66

ISO/IEC 17024

美国国家标准学会程序

“基本要求”

产品认证机构

ISO 9001 / 14001 认证机构

人员认证机构

标准制定机构与美国技术咨询小组

ANSI Accredited Program PRODUCT CERTIFICATION

ANAB ANSI-ASQ National Accreditation Board

ANSI Accredited Program PERSONNEL CERTIFICATION

ANSI Accredited Standards Developer

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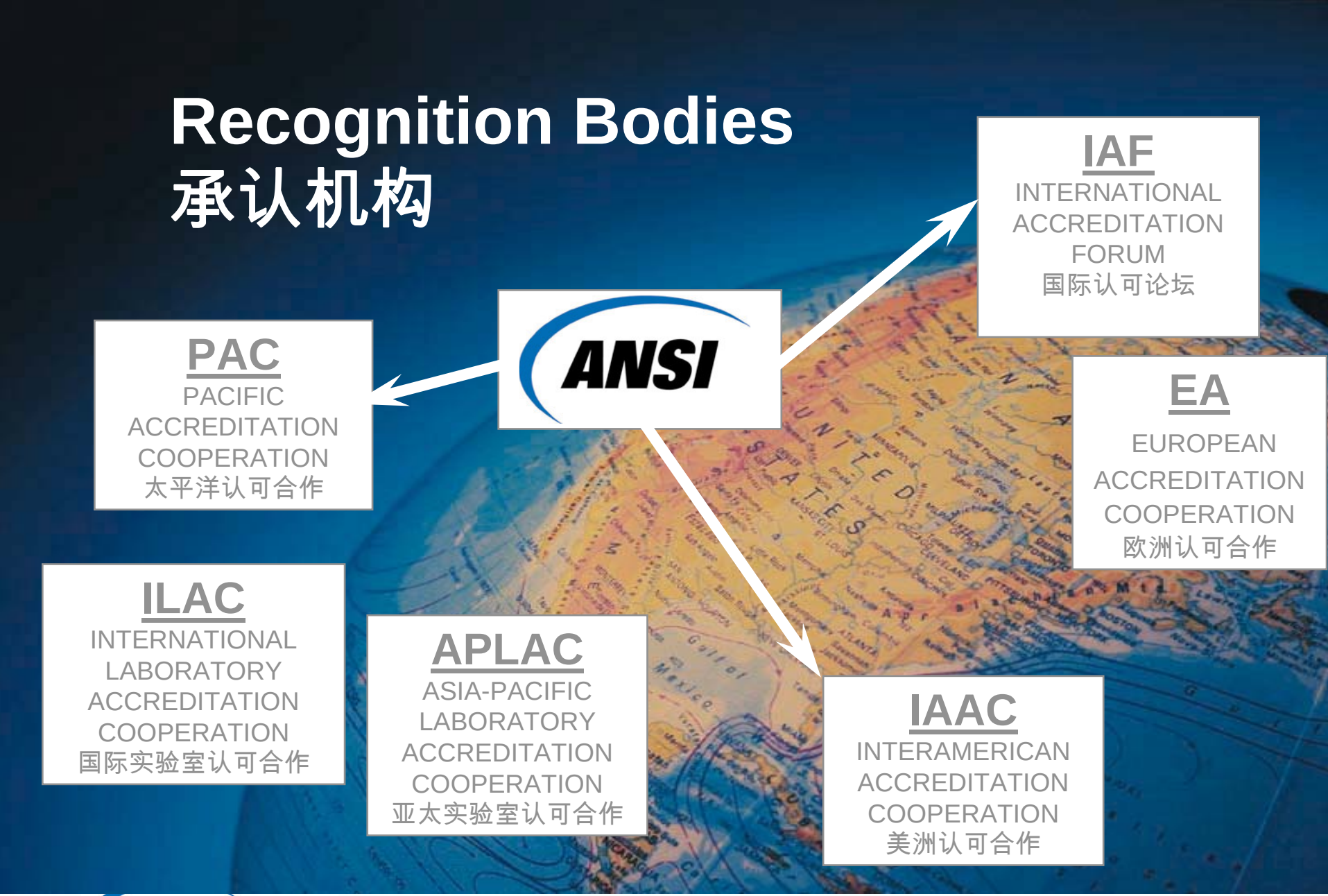
Recognition Bodies
承认机构



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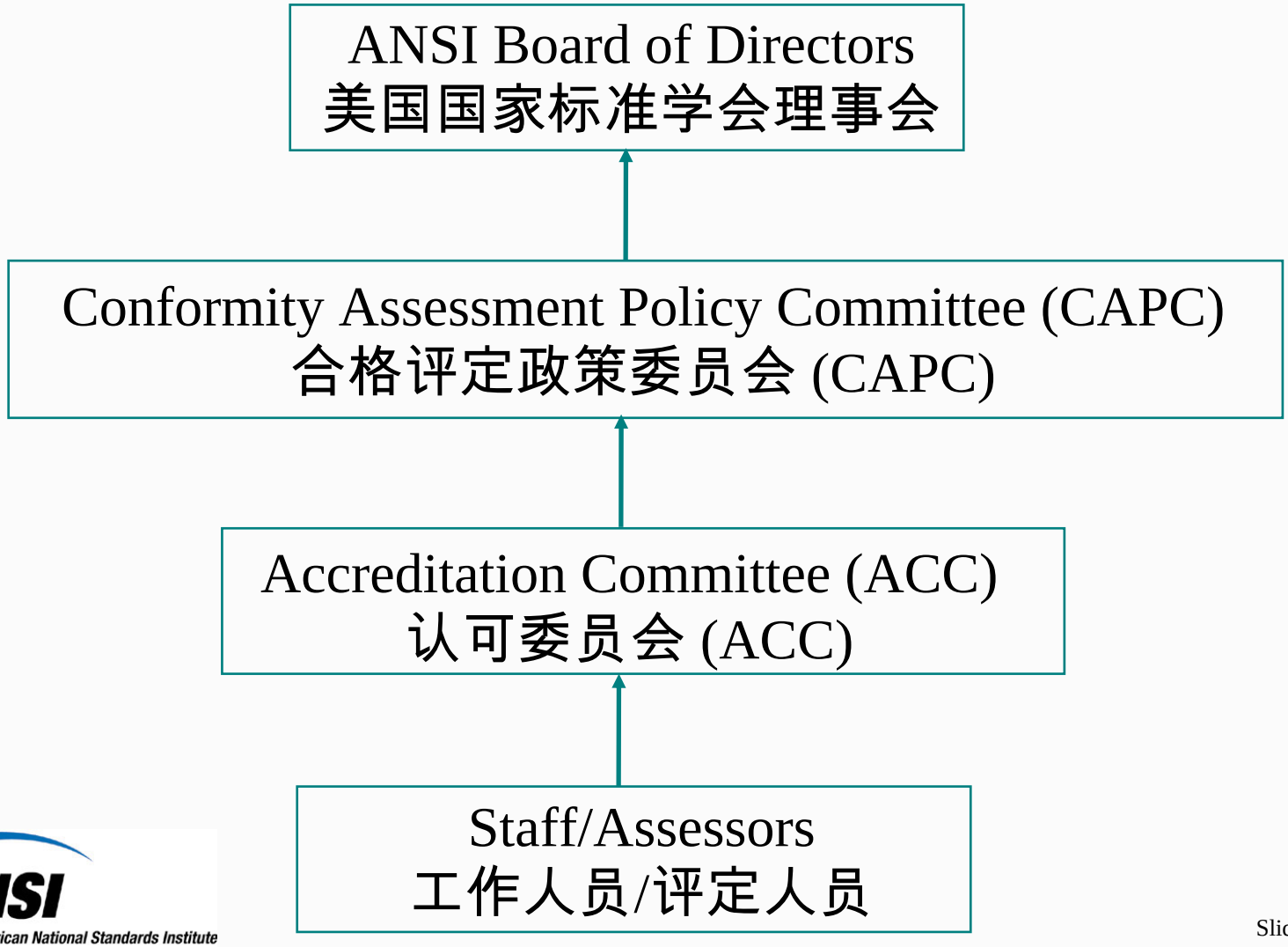
ORGANIZATION
组织机构



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Top Level ANSI Accreditation Documents
美国国家标准学会最高级别的认可文件

- **ANSI-ACP-CA-001:** Policy and Criteria for Accreditation of Certification Programs
- **ANSI-ACP-CA-002:** Manual of Operations for Accreditation of Certification Programs
- **ANSI-ACP-CA-003:** Operating Procedures of the Accreditation Committee

- **ANSI-ACP-CA-001:认证方案的认可政策与标准**
- **ANSI-ACP-CA-002:认证方案的认可工作手册**
- **ANSI-ACP-CA-003:认可委员会的工作程序**

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Accreditation Requirements
认可要求

- ISO/IEC 17011 – Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC Guide 65 General Requirements for bodies operating product certification Systems
- References:
  - ISO/IEC 17025
  - ISO/IEC 17020
  - ISO/IEC guides related to accreditation and product certification
  - Relevant product standards

- ISO/IEC 17011 – 合格评定 –关于认可机构认可合格评定机构的一般要求
- ISO/IEC 指南65 对于执行产品认证系统的机构的一般要求
- 参考件:
  - ISO/IEC 17025
  - ISO/IEC 17020
  - ISO/IEC 与认可和产品认证相关的指南
  - 相关的产品标准

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ANSI-ACP-CA-001
(Policy and Criteria for Accreditation of Certification Programs)
(认证方案的认可政策与标准)

1. Requirements for ANSI as Accreditation Body

   对美国国家标准学会作为认可机构的要求

2. Requirements for Assessment

   评定要求

ISO/IEC 17011 – Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17011 – 合格评定 –关于认可机构认可合格评定机构的一般要求

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ANSI-ACP-CA-002
(Manual of Operations for Accreditation of Certification Programs)
(认证方案的认可工作手册)

1. This Manual of Operations contains detailed procedures for accrediting programs under the ANSI Policy and Criteria for Accreditation of Certification Programs (CA-001). It sets forth the duties and obligations of the parties involved and the necessary inspection and monitoring procedures required to ensure initial and continuing compliance with provisions of the accredited programs, ANSI Policy, and other requirements contained in this document.

1. 该工作手册包括根据美国国家标准学会认证方案的认可政策与标准(CA-001)的规定认可各种方案的详细步骤。它阐明了参与各方的责任和义务，并规定了必要的检查和必需的监督程序，以确保从一开始一直遵守认可方案的规定、美国国家标准学会的政策和本文件包括的其他要求。

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ANSI-ACP-CA-003
(Operating Procedures of the Accreditation Committee)
(认可委员会的工作程序)

Responsibilities

- Policy matter formulation relating to accreditation program operations
- Review and approval of assessment criteria and procedures
- Reviewing the process of evaluation
- Supervising the implementation of accreditation program policies
- Render decisions on granting, maintaining, extending, reducing, suspending and withdrawing accreditation

责任

- 制定与执行认可方案有关的政策
- 审查和批准评定标准和程序
- 审查评价过程
- 监督认证方案政策的执行
- 作出授予、维持、延长、降低、中止和撤销认可的决定

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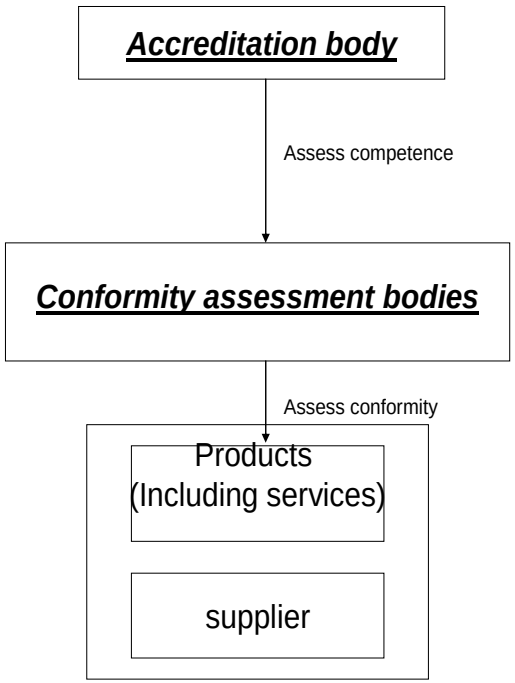
Accreditation Committee (ACC)
认可委员会(ACC)

- Membership
  - Conformity Assessment 6
  - Industry 6
  - Government 4

- 成员人数
  - 合格评定 6
  - 行业 6
  - 政府 4

Accreditation
认证

Flowchart

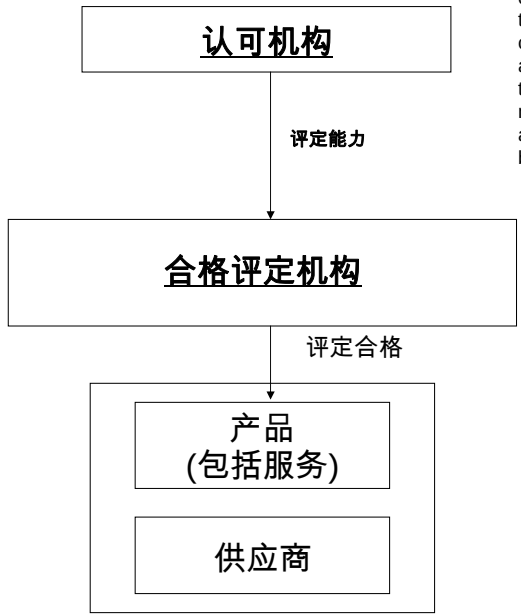


Accreditation bodies assess the competence of CABs. They can facilitate trade by promoting global acceptance of conformity assessment results issued by accredited CABs. This is strengthened if they are peer-evaluated and are members of mutual recognition arrangements among the accreditation bodies.

CABs assess conformity of products (including services) and suppliers to specifications/requirements.

Purchasers acquire products (including services) that conform to specifications or buy from suppliers that conform to specific requirements. Regulators may set requirements for products and suppliers.

流程图



Accreditation bodies assess the competence of CABs. They can facilitate trade by promoting global acceptance of conformity assessment results issued by accredited CABs. This is strengthened if they are peer-evaluated and are members of mutual recognition arrangements among the accreditation bodies.

合格评定机构评订产品(包括服务)和供应商是否符合规范/标准。

买方购买符合规格的产品(包括服务)或者向符合特定要求的供应商购买产品。管理者可能会为产品和供应商提出要求。

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Accreditation Process
认可程序

- Preliminary Letter of Application
- Application
- Preparation for Assessment
- Initial Assessment
- Assessment Report
- Accreditation Committee Renders Decision
- 2-year cycle -- Surveillance & Reassessment

- 初步申请信
- 申请
- 评定准备
- 初步评定
- 评定报告
- 认可委员会做出决定
- 2年的周期—监督与再评定

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Accreditation Decisions
认可决定

- Resolution of Non-Conformities
- Evaluation Task Group Report
- Accreditation Committee Renders Decision
- Appeal Decision
- Announcement of Accreditation
- Surveillance (Continuing Accreditation)

- 做出不合格的决定
- 评价任务小组报告
- 认可委员会做出决定
- 复议决定
- 认可公告
- 监督(继续认可)

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Confidentiality and Disclosure
保密与公布

- All Information Gained Through Accreditation Activities is Treated as Confidential

- Certain outputs/decisions of the Accreditation process are Considered Public Information
  - Application Status
  - Scope
  - Accreditation Status

- 通过认可活动获得的所有信息均被作为机密对待

- 认可过程的某些结果/决定被视为公共信息
  - 申请状态
  - 范围
  - 认可状态

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Accredited Certification Programs
获得认可的认证方案

- TCB Programs
  - 17 current accreditations
  - 2 application pending
- Other Program scopes
  - 18 current accreditations
  - 12 applicants in process

- TCB方案
  - 目前有17项认可
  - 2项申请待批
- 其他方案范围
  - 目前有18项认可
  - 12个申请正在办理中

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Surveillance Assessment
监督评估

To ensure

- Continuing compliance with ANSI requirements
- Evaluate the implementation and verify the effectiveness of corrective actions initiated to resolve non-conformities found previously

- ISO/IEC 17011

要确保

- 一直遵守美国国家标准学会要求
- 评价执行情况，并核实为解决此前发现的不合格情况所采取的纠正行动的效果

- ISO/IEC 17011

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Corrective Action & Continual Improvement
纠正行动 & 持续改进

- Complaints Regarding Accredited Certification Programs
- Complaints Regarding the ANSI Accreditation Program
- Public Notice and Information
- Modification to Accreditation Criteria and Procedures
- Confidentiality and Disclosure of Information

- 对经认可的认证方案的投诉
- 对美国国家标准学会认可方案的投诉
- 公告与信息
- 对认可标准和程序的修改
- 信息的保密和公布

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Appeals Process
复议程序

- Procedure for Appeals
- Consideration by Accreditation Committee
- Appeals must be filed within 30 days of decision
- Accreditation Committee creates appeals panels
- Accreditation Committee renders a decision
- Higher appeals to ANSI Appeals Board possible

- 复议程序
- 认可委员会审议
- 复议必须在决定下达30天之内提出
- 认可委员会成立复议小组
- 认可委员会作出结论
- 可以向美国国家标准学会申诉委员会提出申诉

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ANSI's Role
美国国家标准学会的作用

- NIST/NVCASE Recognition
  - ISO/IEC Guide 61 *General Requirements for Assessment and Accreditation of Certification/Registration Bodies*
  - *Implementation of IAF guidance on ISO/IEC Guide 61*
  - *FCC regulations/requirements*

- NIST/NVCASE承认
  - ISO/IEC指南61 关于认证/注册机构进行评定和认可的一般要求
  - 执行国际宇航联合会对ISO/IEC指南61的指导
  - 联邦通信委员会条例/要求

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ANAB
(ANSI-ASQ National Accreditation body for Management System)
(ANSI-ASQ全国管理系统认可机构)

Customers include BSI, UL, ITS, NSF, API, ASME

- 74 QMS (ISO 9001) Registrars
  - Sector schemes (Auto, Telecom, Aerospace)
- 41 EMS (ISO 14001) Registrars
- 8 applications in process

顾客包括英国标准协会、安全检测实验室公司、 烟草研究所、 国家科学基金会、 美国石油组织、 美国机械工程师协会

- 74处QMS (ISO 9001) 登记处
  - 部门方案 (汽车、电信、航空航天)
- 41处EMS (ISO 14001)登记处
- 8项申请正在办理中

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Personnel Certifier Accreditation
人员认证机构的认可

- ISO/IEC 17024 publication 1 April 2003
- 7 current accreditations to 17024 criteria
- (plus) 3 in FDA - recognized CFP Program
- 20+ new applications resulted from 2004 Marketing Plan
- Great potential: 1,765 known U.S. programs
- Synergies: Government*, Membership, SDOs, Education
  - *FDA/CDC/USDA, DoD Directive, DHS (TSA), VA…

- ISO/IEC 17024 2003 年4月1日出版
- 目前有7项按17024标准进行的认可
- (此外) 食品和药品管理局有3项认可 – 得到CFP方案承认
- 2004年的销售计划产生了另外20个新的申请
- 潜力巨大：美国有1,765个已知的方案
- 协同作用: 政府*, 成员资格, SDOs, 教育
  - *食品和药品管理局/职业发展委员会 /美国农业部, DoD 指示,人口与健康调查 (TSA), VA…

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Thank you

谢谢